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Award Number: W81XWH-05-2-0015

TITLE:

Facilitating smoking cessation and preventing relapse in primary care: Minimizing weight gain by reducing alcohol consumption.

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REPORT DATE:

January 2010

TYPE OF REPORT:

Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) 01-01-2010		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 27 Dec 08 — 26 Dec 09	
4. TITLE AND SUBTITLE Facilitating smoking cessation and preventing relapse in primary care: Minimizing weight gain by reducing alcohol consumption				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-05-2-0015	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)  Mark B. Sobell, Ph.D.				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)  Nova Southeastern University Fort Lauderdale, Florida 33314				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materials Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT A randomized controlled trial was conducted evaluating two smoking cessation interventions for use in primary care settings. Both included the nicotine patch and bupropion (Zyban) if desired. The Brief Counselor Assisted Program (BCAP; 2 in person and 2 telephone counseling sessions) combined motivational interviewing and behavioral counseling with an emphasis on reducing alcohol consumption to minimize weight gain. Participants in the Self-Guided Program (SGP) received a pamphlet discussing change strategies for tobacco cessation, minimizing weight gain, and how to plan for and deal with possible relapses. Current smokers at 3-month follow-up were randomized to receive no further counseling or an in person booster session focusing on obstacles to change. There were 317 participants, 158 in BCAP and 159 in SGP. Follow-up was completed on 92.1% of participants at 3-months, 90.85% at 6-months, and 88.33% at 12-months. Of those found at 3-months, 46.8% of BCAP and 34.4% of SGP participants were non-smokers (p=.031). The difference lost significance when an intent to treat analysis was conducted, but more sensitive analyses (e.g., logistic regression) may still find the difference to be significant. Weight loss and alcohol reduction changes at 3 months were in the predicted direction, but will need to be statistically evaluated by multivariate methods. The current focus is on statistical analyses and dissemination of findings.					
15. SUBJECT TERMS smoking cessation, weight, alcohol, stepped care, primary care					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT  UU	18. NUMBER OF PAGES  15	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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## **Annual Report Award Number W81XWH-05-2-0015**

### **Introduction**

This report summarizes progress made on Award Number W81XWH-05-2-0015 for the third project year, from December 27, 2008 through December 26, 2009. The project, "Facilitating Smoking Cessation and Preventing Relapse in Primary Care: Minimizing Weight Gain by Reducing Alcohol Consumption," involves developing and testing a brief smoking cessation intervention for use in primary care settings. The intervention is intended to help participants stop smoking cigarettes and stay quit by use of motivational interviewing, behavioral counseling and nicotine replacement therapy with an emphasis on reducing alcohol consumption as a strategy for minimizing weight gain related to smoking cessation. Participants are randomly assigned to one of two groups: a Brief Counselor Assisted Program (BCAP), or a Self-Guided Program (SGP), with the nicotine patch and bupropion (Zyban) available to all participants. Participants in the BCAP attend two 30-minute clinic appointments and have two counseling sessions by phone over a period of 8-10 weeks, where tobacco cessation skills are integrated with weight and alcohol reduction strategies. Participants in the SGP receive, in addition to the medication, a pamphlet discussing the most effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to plan for and deal with possible relapses. Current smokers at 3-month follow-up, blocked by original group assignment, are randomized either to receive no further counseling or to attend one clinic booster session focusing on dealing with their individual obstacles to change. All participants are followed up for 12 months. The study addresses three research questions: (1) Does an alcohol reduction strategy designed to minimize weight gain produce higher smoking cessation rates than a control treatment? (2) Does participation in a tobacco cessation program that includes an alcohol reduction component lessen the risk of relapse? (3) Does providing a stepped care intervention (booster) for participants who initially are unsuccessful at stopping improve long-term tobacco cessation rates?

### **Body**

The original Statement of Work was itemized for each investigator and consultant and by necessity, therefore, included considerable redundancy. To make this report better organized and easier to follow, we first discuss progress made toward objectives shared among the investigators. Following that, individual Statements of Work will be presented. The project was approved for a two-year no cost extension in April, 2008.

During Project Year 5 our focus was on completing remaining treatment sessions for participants, continuing to gather follow-up data as specified in the research protocol, double entering and cleaning the large amount of data accumulated, making some initial presentations of preliminary analyses, and planning analyses and publications. Our final sample consists of was 317, with 158 in the BCAP group and 159 in the SGP group. To attain this sample we we had contact with 1,391 total individuals, and of those we screened 1,296 (48 were not screened because they first asked if we offered Chantix,

and when they found out we did not offer it they withdrew from consideration because they could receive Chantix through the smoking cessation program at the base Health and Wellness Center; 47 left initial contact information but never responded to repeated attempts to contact them). The major reasons for screening out were not enough alcohol consumption (549 of 961 total screenouts, or 57%), and wanted Chantix (42), followed by a variety of other reasons such as not wanting to be further contacted. Beside wanting Chantix, which could not be made available because it would have introduced a new medication midway through the trial and possible adverse side effects of Chantix were under investigation at the time, the major reason for screening out was not meeting the alcohol consumption criteria ( $\geq 4$  drinks per week). This was unexpected because, as stated in our original grant proposal, the 2002 DoD Survey of Health-Related Behaviors among Military Personnel reported that, among other things, more than 40% of DoD personnel drank 5 or more drinks at least monthly. In screening for our project, however, more than half of the screenouts resulted from insufficient alcohol consumption. As noted previously, during screening there may have been underreporting of alcohol consumption because our informed consent form was required to include the statement "complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities." This is in contrast to surveys for which respondents typically can remain anonymous. In any event, our final sample was smaller than we had wished but is adequate to test our group comparison.

A strong point of the implementation of the project is that our rate of retrieving data for follow-up has been excellent, especially for a large scale study. At 3-month follow-up, we obtained data on 92.10% of the participants, consisting of 94.97% of the BCAP group and 89.24% of the SGP. Of those found, 46.8% of the BCAP group and 34.4% of the SGP group were non-smokers at three months. This difference was statistically significant ( $p = .031$ ) when evaluated for the 92.1% found for follow up, but it was no longer significant ( $p = .095$ ) when a bare bones intent-to-treat analysis was performed (i.e., every case for which data were not found was considered to be a failure). We anticipate that the finding may still be significant when more sensitive analyses such as logistic regression analyses are conducted as the inclusion of other variables is likely to reduce the error variance somewhat. We also have conducted some very preliminary analyses of changes in weight and in drinking at three months follow-up. These found that the SGP group had gained a mean of 2.22 pounds while the BCAP group had gained a mean of 0.84 pounds. Likewise, the SGP group had reduced its drinking a mean of 2.86 drinks per week (29.1% of baseline) while the BCAP group had reduced its drinking by a mean of 4.29 drinks per week (41.7% of baseline). Both of these differences are in the expected direction but the time X group interaction failed to reach significance in our initial analyses. For weight, there was a significant time effect (baseline to 3-mos),  $F(1,286) = 8.05$ ,  $p=.005$ , but no interaction with condition  $F=2.63$ ,  $p=.106$ . Similarly, for drinks per week there was a significant time effect (baseline to 3-mos),  $F(1,289) = 73.79$ ,  $p<.001$ , but no interaction with condition  $F=2.92$ ,  $p=.089$ . Again, more sensitive analyses may yield significant differences.

The follow-up data collection was just recently completed, and we continued to have excellent data retrieval rates. For the 6-month follow-up, data were collected from 91.14% of the BCAP group and 90.57% of the GSP group, for an overall rate of 90.85%. For the 12-month follow-up, data were collected from 89.24% of the BCAP group and 87.42% of the GSP group, for an overall rate of 88.33%. Often studies only retrieve data on 70%-80% of cases, so our follow-up rate is exemplary.

During the reporting period initial findings were presented in a poster presentation at the annual meeting of the Research Society on Alcoholism in June, 2009, and at the Military Health Research Forum in September, 2009. At the Military Health Research Forum the findings were also presented in a short PowerPoint presentation. Our emphasis during Project Year 6 will be on data analysis and reporting. Beyond the group comparison there are several other central analyses to conduct (e.g., examining weight gain and alcohol reduction) as well as several ancillary but important analyses (e.g., the possible role of depression as a moderating variable). To facilitate the analyses and reporting we are presently preparing a request or modification to our award that will only require internal re-budgeting. Some of what is proposed will include a small revision of the Statement of Work, but that revision will not occur until our proposed modification is approved. Thus, the following Statement of Work is the one approved in May, 2008 with added entries for Dr. Ann Hryshko-Mullen who was appointed Chief of the Clinical Health Psychology Service at Wilford Hall Medical Center during the course of the project.

The following completes the body of this report in a more standard format, reporting achievement of benchmarks in the Statement of Work.

**Mark B. Sobell, Ph.D.**

**Nova Southeastern University**

1. Hire project team members: Y01 M03 Completed
2. Finalize formal protocol, manuals: Y01 M09 Completed
3. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 Completed
4. Monitor compliance with, and integrity of, the treatment protocols: Completed
5. Monitor the quality control of all the data collection required for the project: Completed
6. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: On-going
7. Update previous reports with most recent patient cohort outcome data, in collaboration with the biostatistician: On-going
8. Develop and implement plan to recruit a total of 350-400 subjects into the project by Y04 M12. The plan will include continued on site recruitment at the Kelly Family Medical Clinic and the Wilford Hall Medical Center, use of occasional base wide emails, posters, and other methods of solicitation as approved by the Wilford Hall Medical Center IRB. In addition, on site recruitment will be established at the North Central Federal Outpatient Clinic in San Antonio. Completed
9. Generate the final manuscripts of study results: Y05-06 M12 Ongoing

10. Disseminate results and materials produced by the study: Y05-06 M12 Ongoing

**Linda C. Sobell, Ph.D.**

**Nova Southeastern University**

1. Hire project team members: Y01 M03 Completed
2. Finalize formal protocol, manuals: Y01 M09 Completed
3. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 Completed
4. Train personnel in project intervention: Y01 M12 Completed
5. Monitor compliance with, and integrity of, the treatment protocols: Completed
6. Monitor the quality control of all the data collection required for the project: Completed
7. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: On-going
8. Oversee the conduct of project follow-up: Y04-05 M12 Completed
9. Generate the final manuscripts of study results: Y05-06 M12 Ongoing
10. Disseminate results and materials produced by the study: Y05-06 M12 Ongoing

**Lt Col Alan Peterson, Ph.D.**

**Wilford Hall Medical Center**

1. Review/coordinate IRB approvals: Y01 M09 Ongoing
2. Hire project team members: Y01 M03 Completed
3. Secure office space for WHMC grant staff: Y01 M09 Completed
4. Finalize formal protocol, manuals: Y01 M09 Completed
5. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 Completed
6. Coordinate the training of phone counselors this project: Y01 M12
7. Provide weekly clinical supervision of phone counselors and monitor compliance with, and integrity of, the treatment protocols: Completed
8. Monitor the quality control of all the data collection required for the project: Completed
9. Generate reports on outcomes of each new patient cohort administered the treatment protocols, in collaboration with the biostatistician: On-going
10. Update previous reports with most recent patient cohort outcome data, in collaboration with the biostatistician: On-going
11. Supervise WHMC military and grant staff in assessment and intervention procedures: Y04 M12 Completed
12. Assist in developing and implementing a plan to recruit a total of 350-400 subjects into the project by Y04 M12. The plan will include continued on site recruitment at the Kelly Family Medical Clinic and the Wilford Hall Medical Center, use of occasional base wide emails, posters, and other methods of solicitation as approved by the Wilford Hall Medical Center IRB. In addition, on site recruitment will be established at the North Central Federal Outpatient Clinic in San Antonio. Completed
13. Generate scientific conference presentations of study preliminary results: Y05-06 M12 Ongoing
14. Review/coordinate IRB amendments and annual reports: Y05-06 M12 Ongoing

15. Generate the final manuscripts of study results: Y05-06 M12 Ongoing
16. Disseminate results and materials produced by the study: Y05-06 M12 Ongoing

**Maj Christopher Hunter, Ph.D.**

**Wilford Hall Medical Center**

1. Revise intervention manuals: Y01 M09 Completed
2. Assist in finalization of assessment instruments Y01 M09 Completed
3. Assist in training of military and grant staff to work in the primary care setting Y01 M09 Completed
7. Generate manuscripts of study results: Y05-06 M12 Ongoing

**Maj Christine Hunter, Ph.D.**

**Wilford Hall Medical Center**

1. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Completed
2. Help coordinate, with the biostatistician, the development of the final assessment-outcome measures database: Y01 M09 1. Completed
3. Assist in training of telephone counselors: Y01 M12 Completed  
Assist in weekly supervision of phone counselors: Completed
4. Generate manuscripts of study results: Y05-06 M12 On-going

**Capt Jeffrey Goodie, Ph.D.**

**Wilford Hall Medical Center**

1. Finalize formal protocol manuals: Y01 M09 Completed
2. Assist in training staff to work in primary care setting: Y012 M12 Completed
3. Generate manuscripts of study results: Y05-06 M12 Ongoing

**Keith Haddock, Ph.D.**

**University of Missouri, Kansas City**

1. Provide consultation on development of data base for study and computerize data entry: Y01 M12 Completed
2. Oversee entry of project data, plan for statistical analyses: Y04-05 M12
3. Conduct statistical analyses, consult on interpretation of findings: Y04-05 M12
4. Generate manuscripts of study results: Y05-06 M12

**Carlos Poston, Ph.D.**

**University of Missouri, Kansas City**

1. Provide consultation on development of data base for study and computerize data entry: Y01 M12 Completed
2. Oversee entry of project data, plan for statistical analyses: Y04-05 M12
3. Conduct statistical analyses, consult on interpretation of findings: Y04-05 M12
4. Generate manuscripts of study results: Y05-06 M12

**Timothy Baker, Ph.D.**



### **University of Wisconsin, Madison**

1. Provide consultation on smoking cessation treatment protocol and development of data base: Y01 M12 Completed
2. Help monitor integrity of study implementation: Y03 M06 Not needed
3. Provide consultation on data analysis strategies Y04 M12 Ongoing
4. Provide consultation on interpretation of results: Y04 M12 Ongoing

### **Lt.Col. Ann Hryshko-Mullen, Ph.D.** (Brought forward from the January 2009 annual report)

Dr. Hryshko-Mullen is a Wilford Hall Medical Center staff member added to the research team after the Permanent Change of Station (PCS) of Capt. Jeffrey Goodie, Ph.D. in August 2005.

Dr. Mullen is the Chief of the Clinical Health Psychology Service at Wilford Hall.

1. Maintained Wilford Hall office space for all grant staff personnel: Completed
2. Coordinated with Lackland AFB Tobacco Cessation Program to limit any overlap or conflict with proposed study and ongoing Tobacco Cessation programs: Completed
3. Manuals: Completed
4. Assist in training staff to work in primary care setting: Completed
5. Generate manuscripts of study results: This objective will be a focus of the latter part of Year 5 and of Year 6: Ongoing

### **Key Research Accomplishments.**

- Achieved a very high data retrieval rate for follow-up (3-month follow-up, 92.10% of all participants; 6-month follow-up, 90.85% of all participants; 12-month follow-up, 88.33% of all participants).
- Analyses of 3-month outcomes based on data from the 92.10% of all participants found for follow-up showed that 46.8% of the experimental (BCAP) group and 34.4% of the control (SGP) group were non-smokers. This difference was statistically significant ( $p = .03$ ) but when analyzed using a conservative intent-to-treat analysis (i.e., all cases not found for follow-up were assumed to be still smoking) the difference was not significant ( $p = .095$ ).
- Weight loss and alcohol consumption reduction means were in the direction predicted by the study hypotheses but did not attain significance when analyzed in isolation. The control group gained a mean of 2.22 pounds while the experimental group gained a mean of 0.84 pounds. The control group reduced its drinking a mean of 2.86 drinks per week (29.1% of baseline) while the experimental group reduced its drinking by a mean of 4.29 drinks per week (41.7% of baseline). More sensitive analyses (i.e., including other factors) will further probe this potential mediation effect.

### **Reportable Outcomes**

During the reporting period, two poster presentations and one oral presentation of project results occurred:

Sobell, M.B., Sobell, L.C., Peterson, A.L., Brundige, A., & Hryshko-Mullen, A. Using reduced alcohol consumption as a strategy to minimize weight gain when stopping smoking.

Poster presented at the annual meeting of the Research Society on Alcoholism. San Diego, CA., June 2009.

Sobell, M.B., Peterson, A. L., Sobell, L.C., Hunter, C.L., Hunter, C.M., Brundige, A., Goodie, J.L., & Mendoza, C. (2009). Smoking cessation: minimizing weight gain and preventing relapse by reducing alcohol consumption. Poster presented at the Congressionally Directed Medical Research Programs Military Health Research Forum, Kansas City, MI, September, 2009.

Sobell, M.B., Peterson, A. L., Sobell, L.C., Hunter, C.L., Hunter, C.M., Brundige, A., Goodie, J.L., & Mendoza, C. (2009). Smoking cessation: minimizing weight gain and preventing relapse by reducing alcohol consumption. Oral presentation at the Congressionally Directed Medical Research Programs Military Health Research Forum, Kansas City, MI, September, 2009.

## **Conclusions**

Although the final sample size was less than our target our rates of retrieval of follow-up data have been excellent. Early evaluations of short-term outcomes (3-month) showed a significantly higher smoking cessation rate for the experimental (BCAP) group than the control (SGP) group when only the 92.10% of participants for whom follow-up data were gathered were included in the analyses. When participants for whom data were missing were considered to all be still smoking, the group difference was no longer significant, but this was largely because there was a higher follow-up rate for the experimental group than the controls. At 6-month and 12-month follow-ups the difference in find rates between the groups is much less so those analyses will be less affected when an intent-to-treat approach is used. Also, differences between the groups in terms of amount of weight gain and reduction in alcohol consumption were in the direction of the hypotheses but were not significantly different using isolated analyses. When these factors are combined in more sophisticated analyses such as logistic regression analyses and mediation and moderation analyses it is possible they will reach significance, as the error variance is likely to be greatly reduced. If significance is attained, the findings will add another tool to the arsenal in terms of ways to facilitate smoking cessation. This is especially important for the military where smoking affects readiness and where concern about weight gain related to smoking cessation can be an obstacle to attempting to stop smoking. In this regard, a number of materials developed for use in the experimental condition could be easily disseminated. An example of such an aid is included as an appendix. It is a chart that can be given to smokers that shows the number of calories typically contained in various types of popular alcoholic drinks.

## **References**

See reportable outcomes. No journal articles at this time.

## **Appendices**

Sobell, M.B., Sobell, L.C., Peterson, A.L., Brundige, A., & Hryshko-Mullen, A. Using reduced alcohol consumption as a strategy to minimize weight gain when stopping smoking. Poster presented at the annual meeting of the Research Society on Alcoholism. San Diego, CA., June 2009.



# Using Reduced Alcohol Consumption as a Strategy to Minimize Weight Gain When Stopping Smoking

Mark B. Sobell<sup>1</sup>, Ph.D., Linda Carter Sobell<sup>1</sup>, Ph.D., Alan L. Peterson<sup>2,3</sup>, Ph.D.,  
Antoinette Brundige<sup>3</sup>, M.A., & Ann Hryshko-Mullen<sup>3</sup>, Ph.D.

1. Nova Southeastern University, 2. University of Texas Health Science Center at San Antonio, 3. Wilford Hall Medical Center



## Introduction

- Concern about weight gain is a well-established barrier to smoking cessation.
- In the military, concern about weight gain after quitting is heightened because excessive weight can result in being unfit for service.
- This study targets smoking cessation and minimizing weight gain in patients seen in military primary care settings.
- A unique feature of this study is counseling to reduce alcohol consumption to minimize weight gain after smoking cessation.
- Reduction of alcohol consumption is also included as a treatment component because it is highly correlated with smoking relapse and may increase weight gain due to its relatively high caloric value.
- It is expected that participants counseled to reduce alcohol consumption to minimize weight gain will have higher smoking cessation rates and a lessened risk of relapse than participants who do not receive such counseling.

## Design

- 317 eligible participants, blocked by gender, were randomly assigned to two groups.
- Those who had not stopped smoking at the 3-month follow-up, blocked by initial treatment condition, were randomly assigned to receive or not receive a booster session.
- Follow-up is for 1 year post-treatment.

## 3-Month Outcome

- At the 3-month follow-up, of the 92.1% of participants for whom data were available 40.0% were nonsmokers (7-day window):
  - BCAP = 46.8% Nonsmokers
  - PP = 34.4% Nonsmokers
- The above difference, on the basis of the 92.1% of participants found, is significant:  $\chi^2$  (df = 1,  $N$  = 292) = 4.63,  $p$  = .031.
- If an intent to treat analysis is performed and all missing participants are considered failures, the nonsmoking rates (BCAP = 41.8%; PP = 32.7%) no longer differ significantly:  $\chi^2$  (df = 1,  $N$  = 317) = 2.79,  $p$  = .095.

## Treatment Conditions

### 1. Brief Counselor Assisted Program (BCAP):

Tobacco cessation procedures integrated with weight and alcohol reduction strategies, including nicotine replacement therapy (NRT) and Bupropion SR (Zyban). Two clinic sessions and two phone sessions over 8-12 weeks.

### 2. Pharmacotherapy plus Pamphlet (PP): Self-help pamphlet describing how to implement effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to deal with possible relapses. NRT and Bupropion SR provided.

- The **Booster session** focused on overcoming barriers to smoking cessation, and development of new quit and relapse prevention plans.

## Participants

- Primary care clinics at Wilford Hall Medical Center (San Antonio, TX) are the primary source of participants.
- All participants are eligible military medical beneficiaries.
- Inclusion Criteria:  $\geq 21$  years of age, smoke a mean of  $\geq 5$  cigarettes/day for past year, consume a mean of  $\geq 4$  standard drinks/week, concerned about weight gain, plan to stay in area  $\geq 1$  year.
- Exclusion criteria: Pregnant, trying to become pregnant, breastfeeding; health conditions that contraindicate cessation medication; used weight loss medication within past 6 mos.; at base temporarily; recent or current major depression; DSM-IV alcohol use disorder; other medical contraindications

## Participant Characteristics

Variable	Group	
	BCAP ( $n$ = 158)	PP ( $n$ = 159)
Mean ( $SD$ ) yrs age	37.3 (13.1)	37.6 (12.9)
% Male	69.6	72.3
% Married	62.7	58.5
% White/Caucasian	72.2	68.6
$M$ ( $SD$ ) yrs education	13.7 (1.7)	13.5 (1.8)
% Active duty	63.3	64.8
$M$ ( $SD$ ) Fagerström score	3.7 (2.2)	4.0 (2.1)
$M$ ( $SD$ ) yrs reg. smoker	18.1 (12.9)	18.7 (13.0)
% Health most important reason	79.1	76.7
$M$ ( $SD$ ) no. past quit attempts	6.1 (6.0)	5.9 (6.2)
% Definitely quit next 2 wks.	44.9	47.8
% Def. be nonsmoker in 6 mos.	40.5	43.4
% Def. quit next 6 mos.	79.1	80.4
$M$ ( $SD$ ) readiness quit (1-5)	4.7 (.5)	4.6 (.5)
$M$ ( $SD$ ) goal importance (0-100)	81.8 (15.1)	80.6 (15.4)
$M$ ( $SD$ ) goal confidence (0-100)	82.2 (18.5)	82.0 (19.3)
$M$ ( $SD$ ) concern weight gain (1-10)	6.7 (2.9)	6.7 (3.0)
$M$ ( $SD$ ) days $\geq 5$ drinks past yr.	19.9 (44.0)	16.3 (34.4)

Note: No differences were statistically significant

## Follow-up Rates

Found for 3-mo. follow-up:	92.1%
BCAP	89.2%
PP	95.0%

Sobell, M.B., Peterson, A. L., Sobell, L.C., Hunter, C.L., Hunter, C.M., Brundige, A., Goodie, J.L., & Mendoza, C. (2009). Smoking cessation: minimizing weight gain and preventing relapse by reducing alcohol consumption. Poster presented at the Congressionally Directed Medical Research Programs Military Health Research Forum, Kansas City, MI, September, 2009.





# Smoking Cessation: Minimizing Weight Gain and Preventing Relapse by Reducing Alcohol Consumption



Mark B Sobell, Ph.D., Nova Southeastern University  
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Linda C. Sobell, Ph.D., Nova Southeastern University  
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Christine M. Hunter, Ph.D., National Institute of Diabetes and Digestive and Kidney Diseases  
Antoinette Brundige, M.A., San Antonio Military Medical Center  
Jeffrey L. Goodie Ph.D., Uniformed Services University of the Health Sciences  
Crystal Mendoza, M.A., San Antonio Military Medical Center

## Introduction

- ★ Concern about weight gain is a well-established barrier to smoking cessation.
- ★ In the military, concern about weight gain after quitting is heightened because excessive weight can result in being unfit for service.
- ★ This study targets smoking cessation and minimizing weight gain in patients seen in military primary care settings.
- ★ A unique feature of this study is counseling to reduce alcohol consumption to minimize weight gain after smoking cessation.
- ★ Reduction of alcohol consumption is also included as a treatment component because it is highly correlated with smoking relapse and may increase weight gain due to its relatively high caloric value.

It is expected that participants counseled to reduce alcohol consumption to minimize weight gain will have higher smoking cessation rates and a lessened risk of relapse than participants who do not receive such counseling.

## Specific Aims

- This study will address three research questions:
1. Does a weight gain minimization through an alcohol consumption reduction strategy produce higher smoking cessation rates than a control treatment?
  2. Does participation in a tobacco cessation program that includes an alcohol reduction component lessen the risk of relapse?
  3. Does providing a stepped care intervention for participants who are unsuccessful at stopping in the short-term improve long-term tobacco cessation rates?

## Treatment Conditions

**Brief Counselor Assisted Program (BCAP):** Tobacco cessation procedures integrated with weight and alcohol reduction strategies, including nicotine replacement therapy (NRT) and Bupropion SR (Zyban). Two clinic sessions and two phone sessions over 8-12 weeks.

**Pharmacotherapy plus Pamphlet (PP):** Self-help pamphlet describing how to implement effective behavioral change strategies for tobacco cessation, how to minimize weight gain, and how to deal with possible relapses. NRT and Bupropion SR provided.

The Booster session focused on overcoming barriers to smoking cessation, and development of new quit and relapse prevention plans.

## Participants

- ★ Primary care clinics at Wilford Hall Medical Center (San Antonio, TX) are the primary source of participants.
- ★ All participants are eligible military medical beneficiaries.
- ★ Inclusion Criteria: ≥ 21 years of age, smoke a mean of ≥ 5 cigarettes/day for past year, consume a mean of ≥ 4 standard drinks/week, concerned about weight gain, plan to stay in area ≥ 1 year.
- ★ Exclusion criteria: Pregnant, trying to become pregnant, breastfeeding; health conditions that contraindicate cessation medication; used weight loss medication within past 6 mos.; at base temporarily; recent or current major depression; DSM-IV alcohol use disorder; other medical contraindications.

## Participant Characteristics

Variable	Group	
	BCAP ( <i>n</i> = 158)	PP ( <i>n</i> = 159)
Mean ( <i>SD</i> ) yrs age	37.3 (13.1)	37.6 (12.9)
% Male	69.6	72.3
% Married	62.7	58.5
% White/Caucasian	72.2	68.6
<i>M</i> ( <i>SD</i> ) yrs education	13.7 (1.7)	13.5 (1.8)
% Active duty	63.3	64.8
<i>M</i> ( <i>SD</i> ) Fagerström score	3.7 (2.2)	4.0 (2.1)
<i>M</i> ( <i>SD</i> ) yrs reg. smoker	18.1 (12.9)	18.7 (13.0)
% Health most important reason	79.1	76.7
<i>M</i> ( <i>SD</i> ) no. past quit attempts	6.1 (6.0)	5.9 (6.2)
% Definitely quit next 2 wks.	44.9	47.8
% Def. be nonsmoker in 6 mos.	40.5	43.4
% Def. quit next 6 mos.	79.1	80.4
<i>M</i> ( <i>SD</i> ) readiness quit (1-5)	4.7 (.5)	4.6 (.5)
<i>M</i> ( <i>SD</i> ) goal importance (0-100)	81.8 (15.1)	80.6 (15.4)
<i>M</i> ( <i>SD</i> ) goal confidence (0-100)	82.2 (18.5)	82.0 (19.3)
<i>M</i> ( <i>SD</i> ) concern weight gain (1-10)	6.7 (2.9)	6.7 (3.0)
<i>M</i> ( <i>SD</i> ) days ≥ 5 drinks past yr.	19.9 (44.0)	16.3 (34.4)

*Note:* No differences were statistically significant

## Follow-up Rates

Found for 3-mo. follow-up: 92.1%    BCAP: 89.2%    PP: 95.0%

## 3-Month Outcome

- ★ At the 3-month follow-up, of the 92.1% of participants for whom data were available 40.0% were nonsmokers (7-day window):
  - BCAP    = 46.8% Nonsmokers
  - PP        = 34.4% Nonsmokers
- ★ The above difference, on the basis of the 92.1% of participants found, is significant:  $\chi^2$  (df = 1, *N* = 292) = 4.63, *p* = .031.
- ★ If an intent to treat analysis is performed and all missing participants are considered failures, the nonsmoking rates (BCAP = 41.8%; PP = 32.7%) no longer differ significantly:  $\chi^2$  (df = 1, *N* = 317) = 2.79, *p* = .095.



Example of project-generated smoking cessation materials available for dissemination: Chart on How Many Calories are in a Drink?



## BEER (12 oz)

Anchor Porter	209	Leinenkugel Northwoods Lager	163	Red Hook ESB	179
Anchor Steam	153	Leinenkugel Original	152	Red Hook IPA	188
Anheuser Busch Natural Light	95	Leinenkugel Creamy Dark	170	Rolling Rock Extra Pale	142
Anheuser Busch Natural Ice	157	Leinenkugel Red	166	Rolling Rock Premium Beer	120
Aspen Edge	94	Leinenkugel Light	105	Sam Adams Boston Lager	160
Blatz Beer	153	Leinenkugel Amber Light	110	Sam Adams Boston Ale	160
Blue Moon	171	Lowenbrau Dark	160	Sam Adams Cherry Wheat	166
Bud Dry	130	Lowenbrau Special Beer	160	Sam Adams Cream Stout	195
Bud Ice	148	Magnum Malt Liquor	157	Sam Adams IPA	175
Bud Ice Light	110	Michelob Amber Boch	166	Sam Adams Light	124
Bud Light	110	Michelob Beer	155	Sam Adams Pale Ale	145
Budweiser	145	Michelob Golden Draft	152	Schaefer Beer	142
Busch Beer	133	Michelob Golden Draft Light	110	Schlitz Beer	146
Busch Ice	169	Michelob Honey Lager	175	Schlitz Light	110
Busch Light	110	Michelob Light	113	Schlitz Malt Liquor	185
Carling Black Label	138	Michelob Ultra	95	Sierra Nevada Pale Ale	200
Colt 45 Malt Liquor	174	Mickey's Fine Malt Liquor	157	Sierra Nevada Porter	200
Coors Banquet Beer	142	Miller Genuine Draft	143	Sierra Nevada Stout	210
Coors Light	102	Miller Genuine Draft Light	110	Signature Stroh Beer	153
Genesee Beer	148	Miller High Life	143	Stroh's Beer	149
Genesee Cream Ale	162	Miller High Life Light	110	Stroh's Light	113
Genesee Ice	156	Miller Lite	96	Tuborg Deluxe Dark Export	163
Genesee Red	148	Milwaukee's Best	128	Tuborg Export Quality	156
George Kilian's Irish Red	163	Milwaukee's Best Light	98	Weinhard's Private Reserve	150
Icehouse	132	Milwaukee's Best Ice	144	Weinhard's Amber Light	135
Icehouse	149	O'Doul's	70	Weinhard's Hefeweizen	151
Hamn's Beer	144	Old Milwaukee Light	114	Weinhard's Blonde Lager	161
Hamn's Golden Draft	144	Old Milwaukee Beer	146	Weinhard's Pale Ale	147
Hamn's Special Light	110	Olde English 800 Malt Liquor	160	Yuengling Ale	145
Keystone Premium	108	Olympia Premium Lager	146	Yuengling Porter	150
Keystone Light	104	Pabst Blue Ribbon	153	Yuengling Premium Beer	135
Keystone Ice	143	Pabst Extra Light Low Alcohol	67	Yuengling Light	98
Leinenkugel Honey Weiss	149	Pete's Wicked Ale	174	Yuengling Lager	135



## WINE (4 oz)

Beaujolais	95
Bordeaux, red	95
Burgundy, red	95
Burgundy, white	90
Cabernet Sauvignon	90
Chablis	85
Champagne, dry	105
Champagne, pink	100
Chardonnay	90
Chianti	100
Liebfraumilch	85
Madeira	160
Marsala	80
Merlot	95
Mosell	100
Muscatel	160
Port, ruby	185
Port, white	170
Reisling	90
Rhone	95
Rose	95
Sangria	115
Sauterne	115
Sauvignon Blanc	80
Tokay	165
Zinfandel, red	90
Zinfandel, white	80



## SPECIALTY DRINKS

Alexander	244	Martini	210
Bacardi	144	Mimosa	137
Between The Sheets	141	Mint Julep	115
Black Russian	137	Old Fashioned	156
Bloody Mary	86	Pina Colada	342
Bocci Ball	135	Planter's Punch	184
Brandy Alexander	253	Rob Roy	194
Bronx	191	Rum Sour	128
Bull Shot	91	Rum Swizzle	102
Cuba Libre (Rum & Cola)	127	Rum Toddy	114
Daiquiri	125	Rusty Nail	223
Dubonnet Cocktail	173	Sangria	225
French 75	170	Screwdriver	181
Gibson	207	Sherry Flip	195
Gimlet	110	Side Car	225
Gin & Bitter Lemon	181	Silver Bullet	210
Gin Fizz	130	Singapore Sling	241
Gin Rickey	104	Slow Gin Fizz	167
Gin & Tonic	175	Sombrero	232
Golden Cadillac	250	Stinger	235
Golden Dream	269	Strawberry Daiquiri	150
Grasshopper	255	Strawberry Margarita	210
Harvey Wallbanger	258	Tequila Sunrise	219
Hot Buttered Rum	158	Toasted Almond	286
Irish Coffee	218	Tom Collins	169
Kir	121	Tom & Jerry	252
Madras	123	Vodka & Tonic	175
Mai Tai	310	Vodka Martini	210
Manhattan	183	Whiskey Sour	126
Margarita	185	Zombie	254